

REMARKS

In order to expedite the prosecution of the present application and more particularly point out and distinctly claim the subject matter which Applicants regard as the invention, Claims 28-40 have been amended. The independent claims now recite that the claimed method is directed to the replenishing of electrolyte levels lowered by passive transpiration/perspiration from heat stress and that a carbohydrate source is not contained in the composition. Support for these amendments can be found on the last two lines of specification page 15 and the first three lines of specification page 8. Accordingly, Claim 30 has been canceled. No new matter has been added.

As discussed previously, the instant invention is based on the discovery that the manner in which electrolytes are lowered necessitates a specific manner of replenishing the electrolyte levels. That is, the amounts and types of salt and other minerals lost to sweating and vigorous activities such as sports and exercising are different from the amount of salt and other minerals lost from the human body during passive transpiration/perspiration from heat stress.

The present inventors discovered that rehydration beverages developed for sports purposes were not suitable for replenishing electrolyte levels lowered by passive transpiration/perspiration from heat stress, particularly patients subjected to thermal therapy treatment. Rehydration beverages for sports purposes typically contain a significant energy source, in the form of readily absorbed and metabolized carbohydrates such as glucose, while the great majority of patients undergoing thermal therapy were typically on a diet since weight loss is a secondary benefit sought by most patients utilizing thermal therapy. Additionally, the patients undergoing thermal therapy typically have a high incidence of type II diabetes, since most of them are elderly, and therefore the administration of glucose must be carefully controlled.

As discussed in the present specification, studies have shown that the rehydration needs of young sportsmen and middle aged and elderly people passively undergoing therapeutic heat application are significantly different. That is, during passive heat conditions, much lower amounts of sodium and chloride ions were found in the collected sweat samples than in the physical exercise conditions, whereas the levels of potassium ions were found to be comparable in both conditions. Additionally, it has been noted that patients' skin often appeared to be damaged after repeated application of external heat during thermal mud bath treatments, thereby showing signs of accelerated aging, especially when associated with massive sun light or ultraviolet exposure, which are often used in health spas.

A study performed by Istituto Di Medicina Di Laboratorio that was submitted previously is of record and further emphasizes that the properties and requisites for such a beverage for rehydrating subjects undergoing thermal therapy are profoundly different from beverages developed specifically for the rehydration of subjects engaging in intensive muscular efforts of the sports-agonistic type. Under the heading "2.2. Electrolytes" in this study, it is shown that there is a large difference in the amount of sodium and chloride ions lost under thermal stress conditions and physical stress conditions. The present invention is based on this discovery.

As discussed previously, the Stray-Gundersen reference discloses hypotonic beverage compositions and beverage concentrates adapted for oral administration of water, physiologically essential electrolytes, nutrient materials, carbohydrates and other ingredients to a human body. This reference does not recognize a distinction in the manner in which electrolytes are lowered and, in fact, states that the beverage compositions disclosed there are suitable for use in replenishing water, physiological essential electrolytes, nutrient minerals and carbohydrates to a person who has lost water through dehydration caused by exercise, heat or illness.

In contrast to this reference, currently presented claims expressly exclude carbohydrate sources from being included in the beverage compositions. Since carbohydrates are an essential ingredient in the beverage compositions of Stray-Gundersen, the presently claimed invention clearly is distinguishable thereover.

The Paul et al reference discloses a composition which provides for sustained energy and nutrition to support an anabolic physiological state in humans which comprises a blend of simple sugars and more complex carbohydrates, partially hydrolyzed protein, and, at least, magnesium in the form of an amino acid chelate. Like the previously discussed reference, carbohydrates are an essential ingredient in the composition disclosed there and there is no suggestion that anything beneficial would occur from removing the carbohydrate source from the Paul et al reference or the primary Stray-Gundersen reference.

EP 0 387 042 discloses the formation of alpha-glycosyl rutin and that this compound can be used as a yellow coloring agent, antioxidant, stabilizer, fading-preventing agent, quality-improving agent, preventative, remedy, UV-absorbent and deterioration-preventing agent in foods, beverages, tobaccos, cigarettes, feeds, pet foods, pharmaceuticals for susceptive diseases, cosmetics including skin-refining agents and skin-whitening agents, and plastics, in addition to being useful in vitamin P-enriching agents. However, there is no teaching in this reference that would motivate one of ordinary skill in the art to remove the critical carbohydrates from the compositions disclosed in the previously discussed references. As such, it is respectfully submitted that the currently claimed invention is patentably distinguishable over Stray-Gundersen, Paul et al and EP 0 387 042, either singly or in combination.

Once again, Applicants wish to emphasize that the presently claimed invention is concerned with the replenishment of electrolyte levels lowered by passive

transpiration/perspiration from heat stress and, in particular, thermal therapy treatment. The carbohydrates which are contained in typical "sports drinks" are designed to furnish energy sources, such as carbohydrates, to the consumer of the beverage. Since the consumers of the beverage composition of the present claims undergo thermal therapy to achieve weight loss as a secondary benefit, they're typically on a diet and do not want to consume carbohydrates. As pointed out previously, these people typically also have a high incident of type II diabetes and must carefully control the administration of glucose. Therefore, it is respectfully submitted that the presently claimed invention clearly is patentably distinguishable over the prior art cited by the Examiner. The Examiner is respectfully requested to reconsider the present application and to pass it to issue.

Respectfully submitted,

  
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